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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/02 — A1

(11) International Publication Number: WO 93/20882

(43) International Publication Date: 28 October 1993 (28.10.93)

(21) International Application Number: PCT/US93/03580

(22) International Filing Date: 14 April 1993 (14.04.93)

(30) Priority data:
07/870,820 20 April 1992 (20.04.92) US

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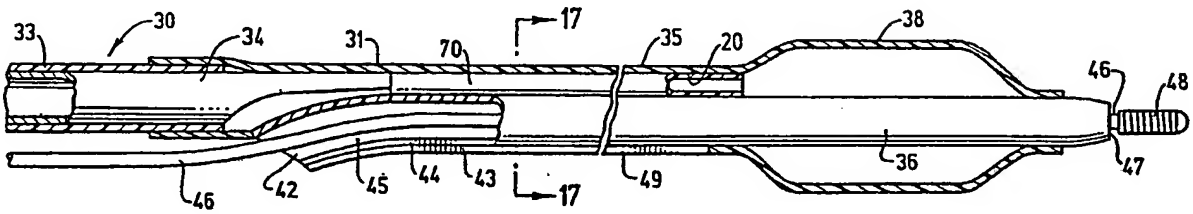
(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: LOW PROFILE DILATATION CATHETER



(57) Abstract

An intravascular catheter, such as a balloon dilatation catheter, which has at least a distal section (35) of an outer tubular member (31) conforms to the shape of and preferably is secured to an inner tubular member (36) over a significant portion thereof to provide a catheter shaft having small transverse dimensions and improved flexibility with little or no loss in pushability. The catheter construction can be employed in a wide variety of catheters.

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LOW PROFILE DILATATION CATHETER

RELATED APPLICATIONS

This application is a continuation-in-part application of copending application Serial No. 07/700,617 filed May 15, 1991, entitled LOW PROFILE DILATATION CATHETER.

BACKGROUND OF THE INVENTION

This invention generally relates to intravascular catheters, such as balloon dilatation catheters used in percutaneous transluminal coronary angioplasty (PTCA).

In classic PTCA procedures, a guiding catheter having a

preshaped distal tip is percutaneously introduced into the cardiovascular system of a patient and advanced therein until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium of the desired coronary artery. The guiding catheter is twisted or torqued from the proximal end to turn the distal tip of the guiding catheter so that it can be guided into the coronary ostium. A guidewire and a balloon dilatation catheter are introduced into and advanced through the guiding catheter to the distal tip thereof, with the guidewire slidably disposed within an inner lumen of the dilatation catheter. The guidewire is first advanced out the distal tip of the guiding catheter, which is seated in the ostium of the patient's coronary artery, until the distal end of the guidewire crosses the lesion to be dilated. The dilatation catheter is then advanced out of the distal tip of the guiding catheter, over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion. Once properly positioned, the balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressures (*e.g.*, generally 4-12 atmospheres) to dilate the stenosed region of the diseased artery. The balloon is then deflated so that the dilatation catheter can be removed from the dilated stenosis and blood flow will resume therethrough.

Further details of guiding catheters, dilatation catheters,

guidewires, and other devices for angioplasty procedures can be found in U.S. Patent 4,323,071 (Simpson-Robert); U.S. Patent 4,439,185 (Lundquist); U.S. Patent 4,468,224 (Enzmann *et al.*); U.S. Patent 4,516,972 (Samson); U.S. Patent 4,438,622 (Samson *et al.*); U.S. Patent 4,554,929 (Samson *et al.*); U.S. Patent 4,582,185 (Samson); U.S. Patent 4,616,652 (Simpson); U.S. Patent 4,638,805 (Powell); U.S. Patent 4,748,986 (Morrison *et al.*); U.S. Patent 4,898,577 (Badger *et al.*); and U.S.Patent 4;827,943 (Taylor *et al.*) which are hereby incorporated herein in their entirety by reference thereto.

The assignee of the present invention, Advanced Cardiovascular Systems, Inc., markets an improved dilatation catheter under the trademark ACS RX® which is described and claimed in U.S. Patent 5,040,548 (Yock), U.S. Patent 5,061,273 (Yock), and U.S. Patent 4,748,982 (Horzewski *et al.*). This dilatation catheter has a short guidewire receiving sleeve or inner lumen extending through a distal portion of the catheter. The sleeve or inner lumen extends proximally a distance of at least about 10 cm and usually not more than about 50 cm from a first guidewire port in the distal end of the catheter to a second guidewire port in the catheter spaced proximally from the inflatable member of the catheter. Preferably, a slit is provided in the wall of the catheter body which extends distally from the second guidewire port, preferably to a

location proximal to the proximal end of the inflatable balloon. The structure of the catheter allows for the rapid exchange of the catheter without the need for an exchange wire or adding a guidewire extension to the proximal end of the guidewire. The design of this catheter has widely praised by the medical profession and has been met with much success in the market place because of the advantages of its unique design.

Another modification, which was introduced into the market place by the assignee of the present application provides a plurality of perfusion ports in the wall forming at least part of the catheter body proximal to the balloon. These perfusion ports are in fluid communication with an inner lumen extending to the distal end of the catheter body. A plurality of perfusion ports are preferably provided in the catheter body distal to the balloon which are also in fluid communication with the inner lumen extending to the distal end of the catheter body. When the balloon on the distal extremity of the dilatation catheter is inflated to dilate a stenosis, oxygenated blood in the artery or the aorta or both, depending upon the location of the dilatation catheter within the coronary anatomy, is forced to pass through the proximal perfusion ports, through the inner lumen of the catheter body and out the distal perfusion ports. This provides oxygenated blood downstream from the inflated balloon to thereby prevent or minimize ischemic conditions in tissue distal to the catheter. As is appreciated by

those skilled in the art, tissue distal to a stenosis is frequently already in jeopardy due to ischemic conditions which may exist. As a result, care must be exercised in sizing the perfusion ports and the inner lumen to ensure that there is adequate flow of oxygenated blood to tissue distal to the catheter to eliminate or minimize ischemic conditions.

A major and continual thrust of development work in the field of intravascular catheters, particularly angioplasty catheters, has been to reduce the profile, *i.e.* transverse dimensions, of such catheters and to improve the flexibility thereof without detrimentally affecting the pushability, particularly in the distal portion, of such catheters. A reduction in profile with no loss in pushability allows an intravascular catheter to be advanced much further into a patient's vasculature and to cross much tighter lesions in the case of angioplasty catheters.

Despite many advances in this field, the need for lower profile intravascular catheters having greater flexibility with little or no loss in pushability remains. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to an intravascular catheter

having a low profile, particularly in the distal portion thereof, and having improved flexibility.

The intravascular catheter of the invention generally includes, at least in the distal portion thereof, an inner tubular member having an inner lumen extending therein and an outer tubular member disposed about the inner tubular member. A substantial part of the distal portion of the outer tubular member is secured or bonded to the inner tubular member along a length thereof. Preferably, the secured part is shaped to conform to the shape of the outer surface of the inner tubular member. Along this length at least about 5% to about 90%, preferably about 30% to about 80%, of the peripheral of the outer tubular member secured to the inner tubular member. The portion of the outer tubular member which is not secured to the inner tubular member along said length forms at least in part a longitudinally extending inner lumen. The bond between the inner tubular member and the conforming portion of the outer tubular member need not be continuous along the length and may be intermittent so long as a significant portion of the outer tubular member is secured to the inner tubular member. The length of the secured section should not be less than 5 mm and is preferably about 10 to about 40 cm. While in a presently preferred embodiment described herein the secured section of the outer tubular member is limited to the distal section of the catheter, the secured

section may extend along essentially the entire length of the catheter.

The distal portion of the catheter is provided with a diagnostic or treatment means, such as an inflatable dilatation balloon for angioplasty, distal to the secured section.

By securing a substantial part of the outer tubular member to the exterior of the inner member along a length thereof to form a fused coaxial design in at least the distal portion of the catheter, the profile of the catheter body in at least one transverse dimension in that area is reduced substantially to thereby provide improved flexibility in at least one direction. Moreover, the secured portions of the inner member and the outer tubular members support one another to provide improvements in the pushability of the catheter. The cross-sectional shape of the catheter wherein the transverse dimension in one direction is substantially larger than the transverse dimension in a second direction at right angles to the first direction can provide substantial improvements in flexibility, trackability and pushability. The maximum dimension of the catheter shaft should be at least 15% greater than the minimum dimension, preferably at least 25% greater. These advantages can also occur with structures different from the fused shaft design described herein, *e.g.* extruded tubular members with the inflation and guidewire lumens in a stacked

configuration where one lumen is disposed above the other lumen in the major transverse dimension of the shaft . Maximum cross-sectional dimensions of the small diameter section of the outer tubular member for coronary dilatation catheters are on the order of about 0.02 to about 0.06 in (0.51 - 1.5 mm). For peripheral arteries this dimension may be larger.

With catheter designs of the invention having the capability for rapid exchangeability, as described in the previously described Horzewski *et al.* patent, there is a tendency for the peel-away slit to open up or expand upon the introduction of the inflation fluid at high pressures into the inflation lumen defined by the unsecured portion of the outer tubular member. To avoid this problem the inflation lumen defined by the unsecured part of the distal section is provided with a support tube so that there is essentially no expansion of the inflation lumen and therefore there is little tendency for the peel-away slit to open up or expand.

The improvements of the invention are applicable to a wide range of intravascular catheters and particularly to essentially all types of dilatation catheters with inflatable or expandable members, such as those described in the patents incorporated herein by reference. These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with

accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view, partially in section, of a balloon dilatation catheter embodying features of the invention.

Fig. 2 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 3-3.

Fig. 4 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 4-4.

Fig. 5 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 5-5.

Fig. 6 is an elevational view, partially in section, of another dilatation catheter embodying features of the invention.

Fig. 7 is a transverse cross-sectional view of the catheter shown in Fig. 6 taken along the lines 7-7.

Fig. 8 is a transverse cross-sectional view of the catheter shown in Fig. 6 taken along the lines 8-8.

Fig. 9 is a transverse cross-sectional view of the catheter shown in Fig. 6 taken along the lines 9-9.

Fig. 10 is a transverse cross-sectional view of the catheter shown in Fig. 6 taken along the lines 10-10.

Fig. 11 is an elevational view, partially in section, of another dilatation catheter embodying features of the invention.

Fig. 12 is a transverse cross-sectional view of the catheter shown in Fig. 11 taken along the lines 12-12.

Fig. 13 is a transverse cross-sectional view of the catheter shown in Fig. 11 taken along the lines 13-13.

Fig. 14 is a transverse cross-sectional view of the catheter

shown in Fig. 11 taken along the lines 14-14.

Fig. 15 is a transverse cross-sectional view of the catheter shown in Fig. 11 taken along the lines 15-15.

Fig. 16 is an elevational view, partially in section, of a modification of the embodiment shown in Figs. 6- 10.

Fig. 17 is a transverse cross-sectional view of the embodiment shown in Fig. 16, taken along the lines 17-17.

Fig. 18 is a transverse cross-sectional view of a modification of the embodiment shown in Fig. 1 wherein two inner lumens are provided in the distal section between the inner and outer tubular members.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1-5 schematically illustrate an over-the-wire dilatation catheter embodying features of the invention. The catheter includes an elongated catheter shaft 10 which has an inner tubular member 11 with an inner lumen 12, an outer tubular member 13 disposed about the inner tubular member and defining therebetween an annular inner lumen 14

which extends through the proximal portion of the catheter shaft. An adapter 15 is secured to the proximal end of the elongated catheter body 10. A relatively inelastic, inflatable balloon 16 is formed as part of the outer tubular member 13 with the distal end of the balloon secured to the distal end of the inner tubular member 11. The balloon 16 may be formed from the same tubing as the outer tubular member 13 as shown in Fig. 1 or it may be made separately and secured to the distal end of a tubular shaft which forms part of the outer tubular member.

The outer tubular member 13 generally has a distal section 17 which is secured to the exterior of the inner tubular member 11 as best shown in Figs. 1 and 3 along a length 18 to provide smaller transverse dimensions in at least one direction. The distal section 17 is secured to the exterior of the inner tubular member 11 with a significant portion of the periphery outer member along the length 18, typically about 50% to about 80%, being secured to the inner member. The unsecured portion 19 of the distal section 17 along the length 18 forms an inflation lumen 20 which is in fluid communication with the interior of the balloon 16 and the annular lumen 14.

The use of the dilatation catheter shown in Figs. 1-5 may generally follow conventional PTCA practices with over-the-wire dilatation

catheters. In the conventional practices a guidewire 21 is backloaded into the inner lumen 12 of the inner tubular member 11 of the catheter body 10 and both the guidewire and the catheter are advanced together through a guiding catheter (not shown) which has been previously disposed within the patient's arterial system, with the distal end of the guiding catheter seated within the ostium of the desired coronary artery. The guidewire 21 is first advanced out the distal end of the guiding catheter into the patient's coronary anatomy until it extends beyond the lesion to be dilated, and then the dilatation catheter is advanced over the guidewire which is being held in its position, until the balloon 16 on the dilatation catheter is properly disposed within the stenotic region so that the lesion is dilated upon the inflation of the balloon. After dilatation, the balloon 16 is deflated and the catheter and the guidewire 21 are withdrawn from the patient. If further treatment or diagnosis is to be conducted, the guidewire 21 can be replaced with an exchange wire before removing the dilatation catheter so that the first catheter can be removed and another advanced into the desired location or an extension wire can be attached to the proximal end of the guidewire in place to perform essentially the same function. For further details see the discussion of exchange wires and extension wires in U.S. Patent 4,827,941 (Taylor *et al.*) which has been incorporated herein by reference.

Figs. 6-10 schematically illustrate another dilatation catheter embodying features of the invention which is quite similar in its most distal structure to the embodiment shown in Figs. 1-5. In the embodiment shown in Figs. 6-10, the catheter shaft 30 includes an outer tubular member 31 which has a two layered proximal portion 32 with an outer plastic tubular jacket or coating 33 which fits tightly, *e.g.* is shrunk fit, onto a tubular element 34 which may be formed of hypotubing. The outer tubular member 31 also includes a distal section 35 which is secured about the inner tubular member 36 as in the previous embodiment. The distal section 35 may be the proximal skirt of the balloon 38, as shown in the drawing, or it may be a separate tubular member. The relatively inelastic balloon 38 is secured by its distal end to the distal end of the inner tubular member 36 which extends through the interior thereof. A significant portion of the interior surface of the distal section 35 along the length 39 is secured to the exterior of the inner tubular member 36 in accordance with the requirements of the invention. The inner tubular member 36 of this embodiment is quite short compared to the inner tubular of the embodiment shown in Figs. 1-5. The unsecured portion of the distal section 35 forms an inflation lumen 40 which is in fluid communication with the lumen 41 in the proximal section 32 of the outer tubular member 31 and the interior of the balloon 38.

In the embodiment shown in Figs. 6-10, the catheter body 30 is

provided a guidewire port 42 which passes through the secured walls 43 and 44 of the inner tubular member 36 and the distal section 35 of the outer tubular member 31 respectively and which is in communication with a relatively short inner lumen 45 extending within the inner tubular member 36. Guidewire 46 extends through the inner lumen 45 and out the proximal port 42 and a distal guidewire port 47. A coil 48 is provided on the distal end of the guidewire 46.

The inner tubular element 34 onto which the outer plastic tubular element 33 is secured is preferably hypotubing and may be formed of conventional stainless steel or a NiTi alloy, particularly a NiTi alloy with superelastic properties, such as described in co-pending application Serial No 07/629,381, filed December 18, 1990, entitled SUPERELASTIC GUIDING MEMBER and assigned to the present assignee.

The catheter construction of this embodiment with a relatively short inner lumen 45, adapted to slidably receive the guidewire 46, eliminates the need for using an exchange wire or a guidewire extension. A peel-away slit 49 is preferably provided in the secured walls 43 and 44 of the inner and outer tubular members 36 and 31 which extend from the guidewire port 42 to a location proximal to the proximal end of the balloon 38. The peel-away slit 49 facilitates the removal of the catheter from the

proximal end of the guidewire 46 when the catheter is to be replaced or exchanged for another catheter and it also eliminates the need for using a guidewire extension or an exchange wire as described in Horzewski *et al.*, which has been incorporated herein by reference. A dual lumen type construction such as described in Horzewski *et al.* may also be used in the portion of the catheter proximal to the guidewire port 42.

There are at least two modes of inserting the dilatation catheter of the embodiment shown in Figs. 6-10 into the patient's coronary anatomy. The first method is for the most part the same as in the prior embodiment, namely, the guidewire 46 is preloaded into the short inner lumen 45 of the inner tubular member 36 of the catheter body 30 and both are advanced through a guiding catheter (not shown) previously disposed within the patient's arterial system with the distal end of the guiding catheter seated within the ostium of a coronary artery. The second mode, frequently called the "bare wire" technique, involves first advancing a guidewire 46 through and out the guiding catheter until it is positioned within the patient's coronary artery across the lesion to be dilated. The proximal end of the guidewire 46, which is outside the patient, is backloaded, *i.e.* inserted into the short inner lumen 45 of the inner tubular member 36 through the distal guidewire port 47 and advanced proximally therein until it exits the proximal guidewire port 42. The proximal end of

the guidewire 46 is held in place and the catheter is advanced over the guidewire through the patient's vascular system until the dilatation balloon 38 on the catheter is positioned across the stenotic region so that the stenosis can be dilated upon the inflation of the balloon. After the dilatation of the lesion, the balloon 38 is deflated and the catheter may be removed from the patient's artery. If other treatments are necessary, the catheter is slidably removed over the guidewire 46, leaving the guidewire in place so that other catheters can be advanced over the in-place guidewire in a similar manner without the need for exchange wires or guidewire extensions.

Figs. 11 through 15 illustrate yet another dilatation catheter embodying features of the invention which provides for the perfusion of blood distal to the catheter during the dilatation of a stenotic lesion. The catheter includes the catheter shaft 50, an inner tubular member 51, with an inner lumen 52, an outer tubular member 53 which is disposed about the inner tubular member and which defines an annular lumen 54 located between the inner and outer tubular members in the proximal portion of the catheter shaft, an adapter 55 secured to the proximal ends of the inner and outer members, and a relatively inelastic balloon 56 which is secured by its distal end to the distal end of the inner tubular member 51. The outer tubular member 53 has a distal section 57, a length of 58 of which is

secured to the exterior of the inner tubular member 51, as previously described in the first two embodiments of the invention. The above-described portion of this embodiment has essentially the same structure as the embodiments shown in Figs. 1-10. The distal section may be formed from the proximal skirt of the balloon 56 or may be formed from a separate tubular element with the proximal end of the balloon being secured to the distal end of the separate tubular element.

The dilatation catheter shown in Figs. 11-15 differs from the other embodiments in that it has a plurality of perfusion ports 59 proximal to the balloon 56 which pass through the bonded walls 60 and 61 of the inner and outer tubular members 51 and 53 respectively and which are in fluid communication with the inner lumen 52 of the inner tubular member 51. Additionally, one or more perfusion ports 62 are provided distal to the balloon 56 through the wall 60 of the inner tubular member 51 and are in fluid communication with the inner lumen 52 extending therein. With this construction, when the balloon 56 is inflated, *e.g.* during an angioplasty procedure, within a patient's vasculature, oxygenated blood is forced to pass through the proximal perfusion ports 59, through the inner lumen 52 and then out the distal perfusion ports 62 to provide oxygenated blood distal to the catheter and thereby avoid the generation of ischemic conditions in tissue downstream thereof or the aggravation of existing ischemic

conditions. The transverse dimensions of the inner tubular member 51 within the secured section are preferably larger than in the embodiments previously discussed to allow for an increased flow of blood therethrough.

The use of the embodiment shown in Figs. 11-15 is essentially the same as the embodiment shown in Figs. 1-5. The only essential difference is that the balloon 56 can be inflated for significantly longer periods, *e.g.* typically about 20-30 minutes but possibly up to 5 hours or more, than the first described embodiment because oxygenated blood is flowing to the tissue distal to the inflated balloon.

The dilatation catheter shown in Figs. 11-15 may be modified by providing a guidewire port at the proximal end of the section 58, proximal to the portion of the small diameter distal section 57 in which the proximal perfusion ports 59 are located, as shown in Figs 6-10. However, the guidewire port should preferably be spaced sufficiently far proximally from the portion of the bonded distal section 57 having the perfusion ports 59 so that the guidewire can be pulled proximally and remain within the inner lumen 52 while the balloon 56 is inflated during the dilatation but not interfere with the flow of blood through the perfusion ports 59 and 62 and the inner lumen 52. After the angioplasty procedure is completed, the guidewire can then be advanced distally through the inner lumen 52 and

out the distal end thereof in order to maintain access to the lesion in case further treatment or diagnosis is necessary or desirable.

The use of the catheter with both perfusion ports and a proximal guidewire port as described above is essentially the same as the use of the dilatation catheter illustrated in Figs. 6-10, but with the additional advantage that long term dilatations are possible.

With those embodiments of the invention which have a slit 49 in the secured section, such as shown in Figs 6-10, to facilitate the removal of the catheter from a guidewire, there is a tendency for the slit to open up when the pressure within the inflation lumen is raised to high levels to inflate the balloon 36 for purposes of dilatation. In these instances, the guidewire can extend through the expanded or opened slit 49 and be caught in the slit when it closes upon the deflation of the balloon so as to preclude independent movement of the guidewire and catheter. To avoid this problem it is preferred to provide a support tube 70 within the inner lumen as shown in Figs 16 and 17. The inner support tube 70 prevents the expansion of the unsecured distal section 35 of the outer tubular member 31 which forms the inflation lumen 40 which causes the slit 49 to expand upon the introduction of high pressure inflation fluid. A filler 71 may be provided to eliminate any voids between the support tube 70 and the unsecured portion of the distal

tubular section 35. Preferably, the support tube 70 is formed of polyimide but tubes formed of other polymers and metals such as superelastic NiTi alloys may be used. The rest of the catheter shown in Figs. 16 and 17 is essentially the same as shown in Figs. 6-10 and the corresponding parts are numbered the same.

The above-described catheters may be made by conventional techniques well known to those skilled in the art. Many suitable techniques are described in the references incorporated herein. The distal section may be formed by heat shrinking the portion of the outer tubular member which forms the distal section onto the underlying inner member. A mandrel (not shown) is disposed in the space between the inner and outer tubular members so that, upon the heat shrinking of the outer tubular member, an inflation lumen is formed through the distal section which is in fluid communication with the lumen in the proximal portion of the catheter shaft and the interior of the balloon. The heat shrinking secures the distal section of the outer tubular member to the inner tubular member. Other means of bonding such as heat bonding or adhesives may be used. A mandrel may also be inserted into the inner lumen of the inner tubular member to support the latter during the heat shrinking of the outer tubular member thereon. Alternate methods may be employed to make the distal section. For example, the distal section of the outer tubular member may be

preformed and then be adhesively bonded to the exterior of the inner tubular member 36.

As shown in Fig. 18, other lumens 80, similar to the inflation lumen may be formed in the catheter shaft, by employing multiple mandrels when heat shrinking the outer tubular member onto the exterior of the inner tubular member. In this embodiment it is preferred to have the secured section extend along the entire length of the catheter so that the adapter on the proximal end would be connected to the all of the individual lumens. In this manner the extra lumens may be employed to deliver drugs or other therapeutic fluids or be used as an additional inflation lumen.

The various components of the catheters and guidewires of the invention can be formed from a wide variety of conventional materials. The inner and outer plastic tubular members may be made from polyethylene, polyimide, polyvinyl chloride and other suitable plastic materials. The hypotubing may be formed of stainless steel, NiTi superelastic alloys or other suitable materials. Composite materials such as described in co-pending application Serial No. 07/241,047, filed September 6, 1988 (which is incorporated herein by reference thereto) may also be used. The balloon may be made from polyethylene, polyethylene terephthalate, olefinic ionomers such as Surlyn® sold by E.I. DuPont, deNemours & Co. and other

polymers and other materials.

The dimensions of the catheters generally follow the dimensions of conventional intravascular catheters. For coronary use the length is typically about 135 cm and the maximum outer diameter of the outer tubular member is about 0.02 to about 0.06 inch (0.51-1.52 mm). In a presently preferred embodiment, the distal secured section of the outer tubular member is long enough (*e.g.* preferably about 10 to about 40 cm) to ensure that it is the only portion of the catheter body proximal to the balloon which exits the guiding catheter and enters the patient's coronary anatomy during intravascular procedures. In other embodiments, the secured section may extend along essentially the entire length of the catheter shaft. The transverse dimensions of the catheter may be larger with catheters for use in peripheral arteries and other locations.

While the invention has been described herein primarily in terms of catheters for coronary angioplasty, the invention may be employed in a wide variety of catheters for insertion into various body lumens. Additionally, modifications and improvements can be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. An elongated catheter for performing intraluminal therapeutic or diagnostic procedures comprising:

a) an inner tubular member having a first inner lumen and a distal end with a port in communication with the first inner lumen, both the inner lumen and the port being adapted to receive a guidewire; and

b) an outer tubular member disposed about the inner tubular member having a distal portion which has about 5% to about 90% of the inner periphery thereof secured to the exterior of the inner tubular member along a length thereof, with an unsecured portion of the outer tubular member defining with the inner tubular member a second inner lumen extending longitudinally between the inner and outer tubular members.

2. The elongated catheter of claim 1 wherein at least about 30% to about 80% of the inner periphery of the distal portion of the outer tubular member is secured to the exterior of the inner tubular member.

3. The elongated catheter of claim 1 wherein a guidewire receiving port extends through the secured section of the outer tubular

member and the inner tubular member and is in communication with the inner lumen of the inner tubular member.

4. The elongated catheter of claim 1 including therapeutic or diagnostic means at a location distal to the secured section.

5. The elongated catheter of claim 4 wherein the therapeutic or diagnostic means is an expandable dilatation member provided on the distal end of the catheter.

6. The elongated catheter of claim 5 wherein the expandable member is an inflatable balloon with an interior in fluid communication with the second inner lumen between the inner and outer tubular members.

7. The elongated catheter of claim 6 wherein the inflatable balloon has a distal end secured to the distal end of the inner tubular member and a proximal end secured to the distal end of a tubular element forming a part of the outer tubular member.

8. The elongated catheter of claim 1 wherein at least one perfusion port extends through the secured portions of the outer tubular

member and the inner tubular member and which is in fluid communication with the inner lumen of the inner tubular member.

9. The elongated catheter of claim 8 wherein at least one perfusion port is provided in the inner tubular member distal to the balloon which is in fluid communication with the inner lumen thereof.

10. The elongated catheter of claim 1 wherein a portion of the catheter body proximal to the secured portion is stiffer than the distal section.

11. The elongated catheter of claim 10 wherein a portion of the outer tubular member proximal to the secured portion thereof is formed of hypotubing to increase the stiffness thereof.

12. A dilatation catheter for performing angioplasty procedures within a patient's arterial system comprising:

a) an elongated catheter shaft having an inner tubular member with a first inner lumen extending therein and a distal end with a guidewire port in fluid communication with the first inner lumen, both of which are adapted to receive a guidewire therein, and an outer tubular member which is disposed about the inner tubular

member and which has a section in a distal part of the catheter shaft with at least 5% but not more than about 90% of the periphery thereof secured to the exterior of an underlying portion of the inner member along a length thereof and with an unsecured portion of the distal section of the outer tubular member defining a second inner lumen between the inner and out tubular members;

b) an inflatable dilatation member distal to the secured section of the outer tubular member having an interior in fluid communication with the second inner lumen and having a distal end secured to the distal end of the inner tubular member which extends through the interior of the balloon; and

c) means to direct inflation fluid from a source through the second inner lumen to the interior of the balloon.

13. The dilatation catheter of claim 12 wherein at least about 30% to about 80% of the inner periphery of the distal section of the outer tubular member is secured to the exterior of the inner tubular member.

14. The dilatation catheter of claim 12 wherein a guidewire receiving port extends through the secured portions of the inner tubular member and the outer tubular member and is in communication with the inner lumen of the inner tubular member.

15. The dilatation catheter of claim 12 wherein at least one perfusion port extends through the secured portions of the inner tubular member and the outer tubular member and is in communication with the inner lumen of the inner tubular member.

16. The dilatation catheter of claim 15 wherein at least one perfusion port is provided in the inner tubular member distal to the balloon which is in communication with the inner lumen thereof.

17. The dilatation catheter of claim 12 wherein a portion of the outer tubular member proximal to the portion thereof which is secured to the inner tubular member is formed of hypotubing to increase the stiffness thereof.

18. A balloon dilatation catheter for performing angioplasty procedures within a patient's arterial system, comprising:

a) an elongated catheter body having an inner tubular member with a relatively short inner lumen extending therethrough and a distal end with a port in communication with the relatively short inner lumen, both of which are adapted to receive a guidewire therein, and an outer tubular member which is disposed about the

inner member and with a length of the outer tubular member in the distal part of the catheter body having at least about 5% but not more than about 90% of the periphery thereof secured to the exterior of an underlying portion of the inner tubular member and taking the shape of the inner tubular member to which it is secured and defining with an unsecured portion of the outer tubular member an inflation lumen along the secured length;

b) an inflatable member distal to the secured portion having a distal end secured to the distal end of the inner tubular member which extends through the interior of the inflatable member;

c) a guidewire port which extends through the secured portions of the inner and outer tubular members and which is in communication with the inner lumen of the inner tubular member; and

d) means to direct inflation fluid from a source through the inflation lumen defined between the unsecured portion of the outer tubular member and the inner tubular member into the interior of the inflatable member.

19. The dilatation catheter of claim 18 wherein the catheter shaft has a relatively stiff proximal portion and a relatively flexible distal

portion.

20. The dilatation catheter of claim 18 wherein at least about 30% to about 80% of the inner periphery of the distal section of the outer tubular member is secured to the exterior of the inner tubular member.

21. The dilatation catheter of claim 18 wherein the proximal portion of the outer tubular member is hypotubing.

22. The dilatation catheter of claim 18 wherein a peel-away slit is provided in the secured section of the catheter shaft extending distally from the proximal guidewire port.

23. The dilatation catheter of claim 18 wherein the inflation lumen defined by the unsecured portion of the outer tubular member has a supporting tubular element therein to prevent the expansion of the peel-away slit in the secured portions of the inner and outer tubular members upon the inflation of the inflatable member.

24. A balloon dilatation catheter for performing angioplasty procedures within a patient's arterial system, comprising:

a) an elongated catheter shaft having an inner tubular

member with an inner lumen extending therein, and an outer tubular member which is disposed about the inner tubular member with a portion thereof in the distal part of the catheter shaft having at least about 5% but not more than about 90% of the periphery thereof secured to the exterior of an underlying portion of the inner tubular member and having an unsecured portion defining with the inner tubular member an inflation lumen along the secured length;

b) an inflatable dilatation member on the distal end of the outer tubular member which has a distal end secured to the distal end of the inner tubular member which extends through the interior of the inflatable member;

c) at least one perfusion port which extends through the secured portions of the inner and outer tubular members proximal to the inflatable member and which is in communication with the inner lumen of the inner tubular member; and

d) means to direct inflation fluid from a source through the inflation lumen defined between the unsecured portions of the outer tubular member and the inner tubular member and into the interior of the inflatable member.

25. The dilatation catheter of claim 24 wherein at least about 30% to about 80% of the inner periphery of the distal section of the outer tubular

member is secured to the exterior of the inner tubular member.

26. The dilatation catheter of claim 24 including a guidewire port which extends through the secured portions of the inner and outer tubular members, proximal to the perfusion ports proximal to the balloon and which is in communication with the inner lumen of the inner tubular member.

27. The dilatation catheter of claim 26 including a peel away slit extending distally from the proximal guidewire port and terminating proximal to the proximal end of the balloon.

28. The dilatation catheter of claim 24 wherein at least one perfusion port is provided through the wall of the inner tubular member distal to the inflatable member.

29. The elongated catheter of claim 1 wherein the outer tubular member is provided with a plurality of unsecured portions which define with the inner tubular member a plurality of inner lumens.

30. The dilatation catheter of claim 12 wherein the outer tubular member is provided with a plurality of unsecured portions which define with the inner tubular member a plurality of inner lumens.

31. The dilatation catheter of claim 24 wherein the outer tubular member is provided with a plurality of unsecured portions which define with the inner tubular member a plurality of inner lumens.

32. An intravascular catheter comprising an elongated catheter shaft having a plurality of inner lumens extending therein with at least one outer dimension of the shaft in a first transverse direction being substantially greater than another outer dimension of the shaft in a second transverse direction at a right angle to the first direction.

33. The intravascular catheter of claim 32 wherein the outer dimension of the shaft in the first transverse direction is at least 15 % greater than the outer dimension in the second transverse direction.

34. The intravascular catheter of claim 32 wherein the outer dimension of the shaft in the first transverse direction is at least 25 % greater than the outer dimension is the second transverse direction.

35. The intravascular catheter of claim 32 wherein the shaft has at least two inner lumen extending therein which are in a stacked configuration.

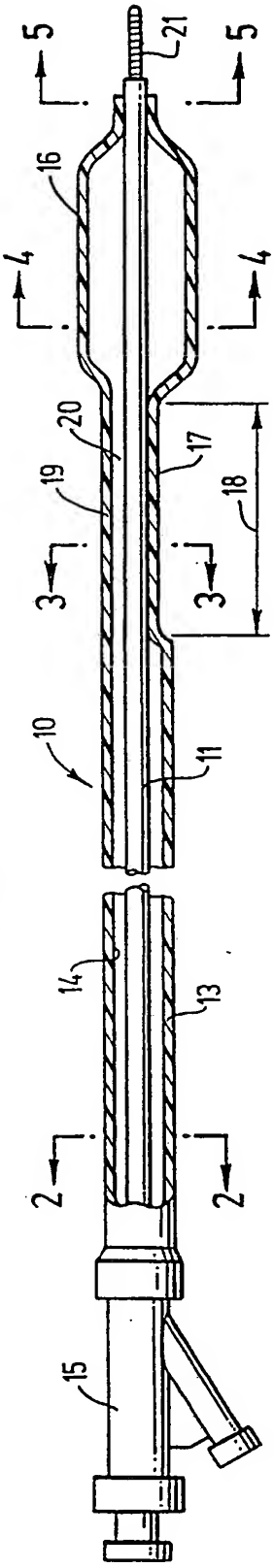

FIG. 1

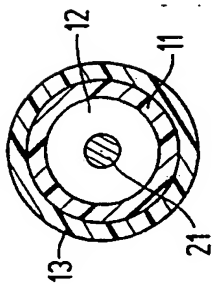

FIG. 5

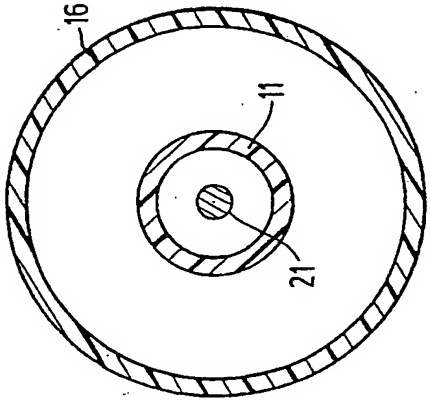

FIG. 4

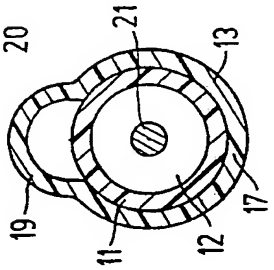

FIG. 3

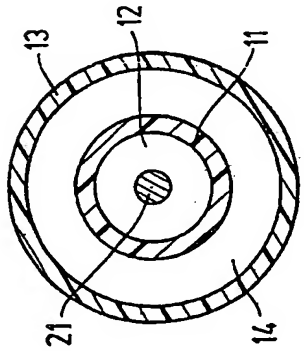

FIG. 2

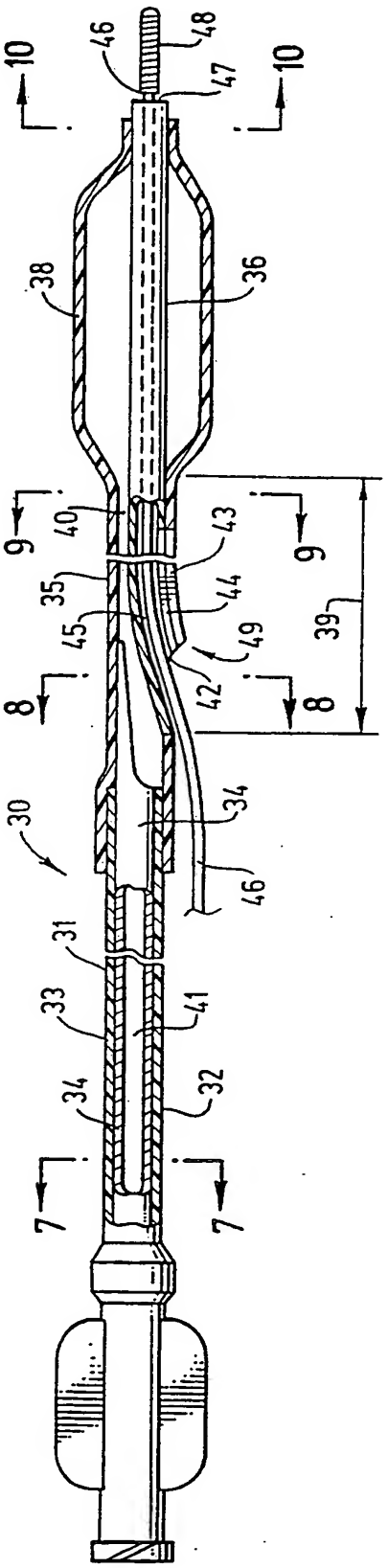

FIG. 6

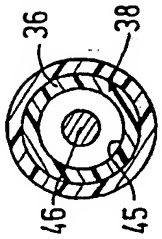

FIG. 10

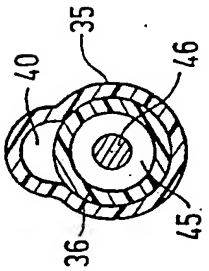

FIG. 9

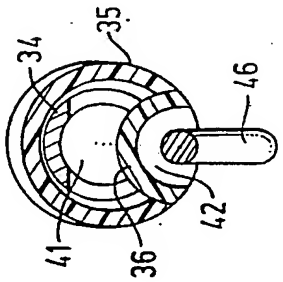

FIG. 8

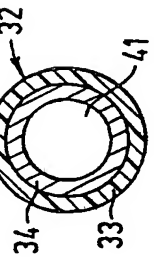

FIG. 7

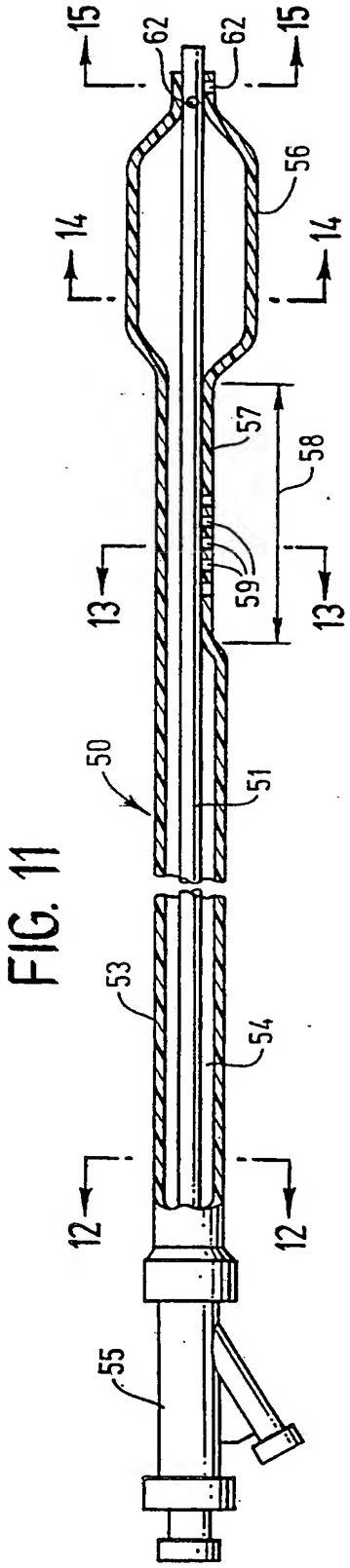

FIG. 11

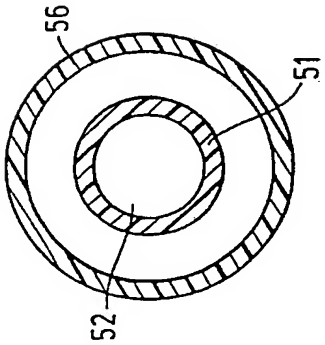

FIG. 14

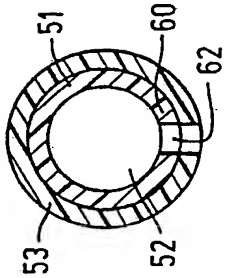

FIG. 15

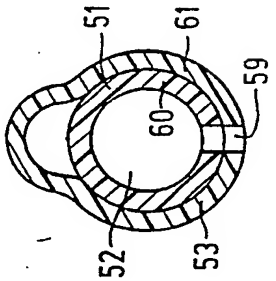

FIG. 13

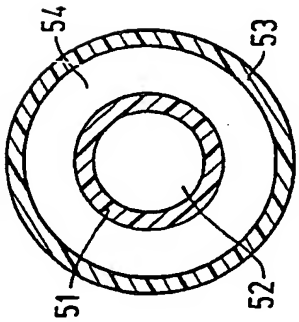

FIG. 12

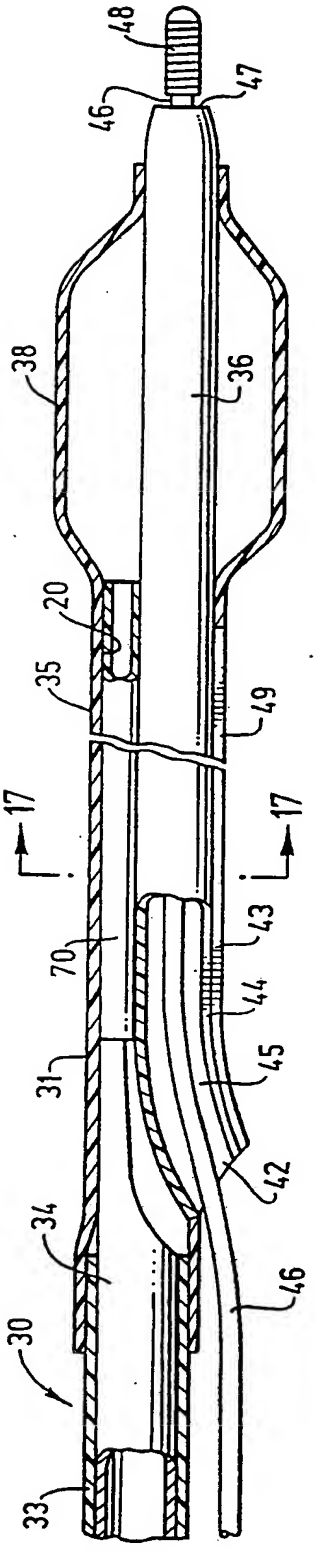

FIG. 16

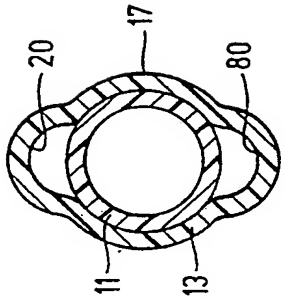

FIG. 18

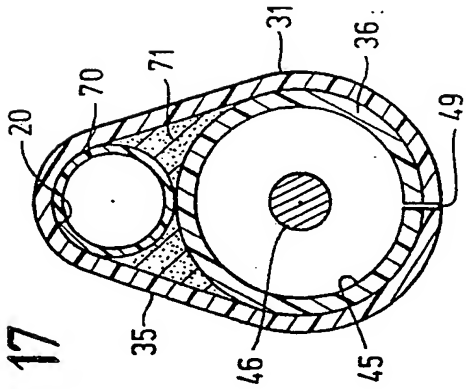

FIG. 17

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 93/03580

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M29/02

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	US,A,4 892 519 (SONGER ET AL.) 9 January 1990 see claims; figures	1-10, 12-16, 24-26,28
A	US,A,4 877 031 (CONWAY ET AL.) 31 October 1989 see abstract; figures	1-35
A	EP,A,0 374 859 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 27 June 1990 see column 3, line 6 - line 9	11,17,21
A	EP,A,0 441 384 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 14 August 1991 see column 7, line 10 - line 14; figures 1,3	18, 22-23,27

-/--

[10] Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
12 AUGUST 1993	24.08.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category°	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,3 915 171 (SHERMETA) 28 October 1975 see column 3, line 31 - line 46; figure 6	29-35

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9303580
SA 74052

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 12/08/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4892519	09-01-90	None	
US-A-4877031	31-10-89	None	
EP-A-0374859	27-06-90	US-A- 4998917 JP-A- 2271875	12-03-91 06-11-90
EP-A-0441384	14-08-91	JP-A- 5084304	06-04-93
US-A-3915171	28-10-75	None	